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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SOUAYA, JEHANNE E

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 10/23/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/724,678**

Applicant(s)  
**Lee et al.**

Examiner  
**Jehanne Souaya**

Art Unit  
**1634**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 29, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above, claim(s) 6-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because of the following informalities: Figure 1 contains a sequence that does not have a sequence identifier either in the figure or the "Brief Description of the Figures". This objection can be easily overcome by specifying in the "Brief description of the Figures" that the sequence is SEQ ID NO 16.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite in the recitation of "capable" as it is unclear whether the claimed function of 'specially hybridizing' is a property of the claimed primers or whether it only could be.

Claim 5 is indefinite in the recitation of "corresponding to the sense strand". It is unclear if the term refers to a homologue of the sense strand or to the antisense strand. Therefore, the metes and bounds of the claim are unclear.

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Claim 23 is indefinite as it is unclear how the kit further comprises at least one synthetic nucleotide sequence according to claim 5, however, the limitations of claim 23 are such that specific combinations of primers according to claim 1, ie: SEQ ID NO 1 and SEQ ID NO 6, would result in no synthetic nucleotide sequences according to claim 5 present in the kit. It is further noted that in such case, claim 23 does not further limit claim 22.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 5 is rejected under 35 U.S.C. 102(a) as being anticipated by Accession number AF136379 (June 2000).

AF136379 teaches a sequence of 7410 nucleic acids which comprises SEQ ID NO 13 (positions 1456-1483) and SEQ ID NO 14 (positions 1392-1421). AF136379 is a sequence that is the complete CDS for enterovirus 71 isolate NCKU9822 polyprotein, and would hybridize specifically to an enterovirus antisense strand (it is noted that the recitation of "corresponding to the sense strand" has been interpreted to encompass the antisense strand). It is further noted that

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the limitation of "synthetic nucleotide construct" does not carry patentable weight to distinguish the claimed sequences over that of AF136379.

6. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Accession number Z78129 (August 1997).

Z78129 teaches a sequence of 358 nucleic acids which comprises SEQ ID NO 9 (positions 260-286). Z78129 is a sequence that is part of the 5' untranslated region of Enterovirus 70, strain B2592, and would hybridize specifically to an enterovirus antisense strand (it is noted that the recitation of "corresponding to the sense strand" has been interpreted to encompass the antisense strand). It is further noted that the limitation of "synthetic nucleotide construct" does not carry patentable weight to distinguish the claimed sequences over that of Z78129.

7. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Accession number U55870 (May 1996).

U55870 teaches a sequence of 83 nucleic acids which comprises SEQ ID NO 10 (positions 15-47) and SEQ ID NO 11 (positions 48-75). U55870 is a sequence that is part of the 5' NTR sequence of an enterovirus species, would hybridize specifically to an enterovirus antisense strand (it is noted that the recitation of "corresponding to the sense strand" has been interpreted to encompass the antisense strand). It is further noted that the limitation of "synthetic nucleotide construct" does not carry patentable weight to distinguish the claimed sequences over that of U55870.

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***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-5 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kilpatrick (US Patent 6,168,917: 102(e) date July 9, 1999) in view of Accession numbers U22521 (Jan 1997), AF177911 (Sep 1999), AF136379 (Jun 2000), U55870 (May 1996) and Z78129 (Aug 1997) and further in view of Accession number E30248 (from JP 1999346799, published Dec 1999).

Kilpatrick teaches a method that uses specific primer pairs to detect different enterovirus serotypes, including enterovirus 71 and coxsackievirus A16 (see col.2, fig 5, col 11, table 1, and

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cols 16 and 17). Kilpatrick specifically teaches that there is a need for a detection system that identifies and differentiates most or all enterovirus serotypes and that such would improve the speed and accuracy of processing samples and increase the sensitivity of detecting minority populations of enteroviruses in mixed serotype cultures (col. 6, lines 31-35). Kilpatrick specifically teaches methods of developing suitable primer pairs, including the use of degenerate primer pairs which incorporate mixed base residues or deoxyinosine to increase the speed and sensitivity of detecting non polio enteroviruses (col. 7, lines 40-41, and col 15). Kilpatrick teaches an amino acid alignment of different non polio enteroviruses including enterovirus 71 and coxsackievirus A16 (fig 2a-2d) and further teaches that nucleotide sequences of such were known at the time of the invention (col. 10, lines 16-30). Kilpatrick teaches how to develop specific primer pairs to identify such serotypes in PCR based methods of detection and differentiation (col 11-13) using regions of differing nucleic acid sequence homology among nucleotide capsid sequences (col 12, lines 26-67 and col 10 lines 31-32) of different serotypes. Further, Kilpatrick teaches providing such primer pairs in kit format for use in practicing the method of Kilpatrick (para bridging cols 13 and 14). It is noted that Kilpatrick does not teach primer pairs or kits comprising the claimed primer sequences. However, the sequence of enterovirus 71 and coxsackievirus A16 were known in the art at the time of the invention, and specifically the following Accession numbers were available to the ordinary artisan: U22521 teaches the complete sequence of Enterovirus 71 BrCr, AF177911 teaches the coxsackievirus A16 polyprotein gene (which contains SEQ ID NO 14: positions 1346-1475, and SEQ ID NO 15,

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positions 1392-1422), AF136379 teaches Enterovirus 71 polyprotein mRNA, U55870 teaches an Enterovirus 5' non translated region sequence which contains SEQ ID NOS 10 and 11 and Z78129 teaches a region of Enterovirus 70 RNA 5' untranslated region (which contains SEQ ID NO 9). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to develop primer pairs and nucleotide sequences to detect Enterovirus 71 and Coxsackievirus A16 and to package such sequences in kit format as Kilpatrick specifically teaches primer pairs that detect specific serotypes including Enterovirus 71 and Coxsackievirus A16 and teaches packaging such in kit format. The ordinary artisan would have been motivated to develop such sequences as Kilpatrick specifically teaches a need for such a system. Although Kilpatrick in view of the recited accession numbers do not teach the specific primer pair and nucleotide sequences of the claimed invention, armed with the teachings of Kilpatrick, the ordinary artisan would have been able to develop primer pairs and nucleotide sequences that would specifically detect Enterovirus 71 and Coxsackievirus A16 given that the sequences of such serotypes were known in the art at the time of the invention and Kilpatrick specifically teaches how to develop specific primer pairs and nucleotide sequences specific for certain serotypes (it is noted that accession number E30248 teaches the reverse complement of SEQ ID NO 7, which is used to identify serotypes of enterovirus). Such primer pairs and nucleotide sequences would be considered functionally equivalent in a method of detecting Enterovirus 71 and Coxsackievirus A16, absent evidence to the contrary.



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*Conclusion*

10. No claims are allowable over the cited prior art.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Jehanne Souaya*  
Jehanne Souaya  
Patent examiner  
Art Unit 1634  
*Oct 16, 2002*